

Chapter Fourteen

PESTICIDE IMPORT AND EXPORT PROGRAM

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PESTICIDE IMPORT AND EXPORT PROGRAM

AUTHORITY

Section 17(a) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) states in part:

Notwithstanding any other provision [of] this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act -

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1)(A), (C), (D), (E), (G), and (H), 2(q)(2)(A), (B), (C)(i) and (iii), and (D), 7, and 8 of this Act; and

(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act.

A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

Section 17(c) of the Act directs the Secretary of the Treasury to: notify the Administrator of the arrival of pesticides and devices; and deliver to the Administrator (upon his/her request) samples of pesticides or devices which are being imported into the United States.

[See Section 17 of FIFRA for complete statute information, and the supporting regulations at 40 CFR 168, Subpart D, and additionally, 19 CFR 12.110 - 12.117 (Exhibit 14-1 and 14-5)].

OBJECTIVE

The objective is to ensure that pesticides and devices imported into or exported from the United States comply with the requirements of FIFRA. Imported pesticides and devices that are found not to be in compliance must be detained and, if those items are not brought into compliance, must be refused entry.

REQUIREMENTS

Exports

All exported pesticides are subject to the labeling requirements of FIFRA. In addition, certain label items must be in both the English language and in the language of the importing country, if English is not the predominantly spoken language or the language used in conducting official business in the importing country.

The following label items are subject to the bilingual requirement:

- < The warning and caution statements.
- < The ingredient statement.
- < Where required, the word “poison” and the statement of practical treatment (first aid).

For the purposes of regulating the exportation of pesticides, the Export Policy divides exported pesticides into categories, as outlined below, with differing requirements for each category.

EPA Registered Pesticides That Are Exported with EPA Registered Labels.

The only additional requirement for the exportation of EPA registered pesticides with EPA approved labels, is that certain of the label items (the warning and caution statements, the ingredient statement, and when required, the word “poison” and the statement of practical treatment) must be in both the English language and in the language of the importing country, if English is not the predominantly spoken language or the language used in conducting official business in the importing country.

Unregistered Pesticides Which Are Similar in Use and Composition to a Registered Pesticide, as Defined in the Export Policy.

The use of bilingual labeling when being exported to non-English speaking countries.

The labels must include the statement “Not Registered for Use in the United States of America.”

A signed statement from the foreign purchaser of the unregistered pesticide acknowledging that the purchaser understands that the pesticide is not registered for use in the United States and cannot

be sold in the United States. This statement must be obtained prior to the first shipment of a particular pesticide to a particular purchaser for each country annually i.e. Foreign Purchaser Acknowledgment Statement (FPAS)..

PROCEDURES

Exports

Inspection and Sampling

Pesticides may be exported from the United States whether they are registered, unregistered, canceled or suspended – provided certain criteria are met. Export Inspections are generally conducted at producing establishments, but pesticides intended for export may be encountered during port visits or Marketplace Inspections where pesticides might be stored pending export.

Procedures

For routine inspections, the general requirements are to verify compliance with the export regulations. A checklist (Exhibit 14-2) is provided to assist inspectors to ensure that all requisite activities have been covered. For “For Cause” Inspections, follow the specific instructions on the EPA referral.

Most export inspections will be included along with section 8 Books and Records inspections conducted at pesticide producer establishments. These will involve the review and collection of export pesticide labels, shipping documents, sales invoices, statements and other documents which can be used to document the export of pesticide products. Pesticides for export can be contract produced and shipped domestically to another company for exportation. In these cases it may be necessary to conduct the inspection at the pesticide-producing establishment and the company that is actually responsible for the exportation of the product. (For more information on Producer Establishment Inspections see Chapter 7 of this manual).

The inspector shall secure a copy of the Foreign Purchaser Acknowledgment Statement (FPAS) for each unregistered pesticide and cross-reference the date of the exporters receipt of the FPAS with the actual date of sale or distribution of the unregistered pesticide, whether that distribution be from the contract manufacturer, various warehouse facilities, shipping contractors etc. The unregistered pesticide **cannot legally move until the FPAS is received by the exporter.** Any sale or distribution of the unregistered pesticide prior to the exporters receipt of the FPAS is unlawful, unless otherwise exempted by FIFRA and FIFRA regulations.

During export inspections the inspector, through discussions with responsible company officials and subsequent review of company records, must be able to clearly document the items identified below. When information is not available or cannot be clearly

documented by obtaining copies of records, the inspector must obtain statements from responsible company officials that clearly document the procedures used by the company when exporting pesticides.

Some of the information to be obtained during these inspections may be claimed as FIFRA CBI. Only Federal FIFRA CBI cleared inspectors may obtain, copy, view, or collect CBI materials. If the establishment-facility is inspected by an authorized State inspector, using State credentials, any CBI information/documents in question must be: (1) only provided to the State inspector on a consensual or voluntary basis and only after the State inspector has informed the establishment they are cleared to view, obtain, or copy CBI under State statute or (2) if claimed FIFRA CBI, request the responsible company official to send the information/documents directly to the EPA Regional FIFRA Document Control Officer (DCO). The inspector must provide the responsible company official with a listing of all requested documents/exhibits to be sent to the regional office, and notify the Regional DCO that the company is sending the information.

Pre-inspection Activities (Regional Office Function)

The Federal EPA inspector should conduct the following pre-inspection activities:

- < Review and copy section 7 pesticide establishment production data submitted to the region on EPA Form 3540-16 for all unregistered products exported for the targeted calendar year(s).
- < Develop a comprehensive list of unregistered products exported in the targeted calendar year(s) by the targeted establishment. Regional listings of unregistered products, product name and establishment name/address should be obtained from the Section Seven Tracking System (SSTS).
- < Review and copy all “confidential statements of formula” (CSF) or chemical formulation statements if available at the region for all products identified above. Develop a list of all unregistered products that were found not to have “product formulas” on file and give it to the regional/State inspector prior to the inspection (so that the inspector can obtain any missing formulas at the time of the inspection). Note on this listing if “product formulas” were not submitted to the region along with the production data in EPA Form 3540-16 for each calendar year.

On-Site Inspection Activities (Regional/State Function)

Entry

Present credentials and issue a Notice of Inspection to the agent-in-charge. The reason for the inspection must be stated and, if a violation is suspected, and the suspected violation must be noted in writing on the Notice of Inspection.

For each unregistered product exported in the targeted calendar year(s), the inspector must:

- < Obtain evidence that clearly shows the company responsible for the product and its export. Obtain evidence that describes past and present corporate relationships, such as mergers, takeovers and/or other corporate transactions and any agreement expressing the nature and responsibilities between the companies involved in the export of the pesticide/device.
- < Obtain copies of the “confidential statement of formula” (CSF) if available; otherwise, obtain a copy of the complete formula of the product. (Note: The CSF contains confidential business information (CBI) and cannot be viewed, copied, or obtained by a State inspector unless authorized by statute and State credentials. An EPA inspector cannot view/copy the CSF unless cleared for CBI).
- < Obtain copies of the specifications or directions of the foreign purchaser for the production of the product [40 CFR Part 169.2(h)(1)].
- < Obtain copies of label(s) and supplemental labeling, including bilingual label(s), used for each importing country [40 CFR Part 169.2(h)(2)]. If product label(s)/labeling are not available, obtain bin labels/labeling. In either case, the inspector shall obtain a statement from the responsible company official certifying that the labels/labeling collected are identical to those used on the exported product.
- < If a particular product label is being used for more than one country, the statement must include the name of each country. If unregistered pesticides are packaged, labeled and released for shipment at the time of the inspection, obtain sample labels/labeling and photographic evidence of all such products.
- < Obtain copies of all foreign purchaser acknowledgment statements for the first shipment each year of a particular product to a particular purchaser for each importing country [40 CFR Part 169.2(h)(3)].
- < Obtain documentation showing the dates and amounts of each unregistered product shipped and country of destination. (e.g. bills of lading, invoices, consignee lists) [40 CFR Part 169.2(d)]. Only federal EPA inspectors or authorized State/tribal inspectors using State or tribal credentials and State or tribal authority can obtain this documentation.
- < Note in the inspection report/findings if any of the documents above were not maintained by the facility. If the facility does not maintain records listed above, obtain a statement from the responsible official as to why the records

were not maintained by the facility and the actual location of the records/documents, if known. The inspector must request that copies of all missing records be sent to the inspector or at a minimum to the Regional office.

- < In instances where the facility/establishment claims that a product is “substantially similar” to a registered product and a foreign purchaser acknowledgment statement was therefore not required.
 - Obtain a statement from the responsible company official certifying that the unregistered product is “substantially similar in composition and use” to one or more federally EPA registered products, and specifically list each registered product(s) that the company claims as similar to its unregistered product by product name and EPA Reg. No.(s) along with the rationale for making such a claim.

- < For instances where the facility/establishment claims that a product is for “research and development” or “experimental” purposes and a foreign purchaser acknowledgment statement was therefore not required.
 - Obtain a statement from the responsible company official specifically describing the basis for any such claims.

The FIFRA export inspection checklist (Exhibit 14-2) will assist the inspector covering all the above items.

Imports

Imported pesticides and devices are subject to the same registration, labeling requirements, and exemptions as domestically produced pesticides and devices.

Import of Unregistered Pesticides

Under certain conditions, unregistered pesticides will be allowed to enter the United States. A Notice of Arrival of Pesticides and Devices (NOA), EPA Form 3540-1 will be required for these unregistered products. These conditions are found in 40 CFR 152.30 and in Pesticide Registration (PR) Notice 99-1 (Exhibit 14-3). An unregistered pesticide may be imported if:

- (1) it is transferred between registered establishments operated by the same producer (all EPA label requirements must be met;
- (2) if the establishments are not operated by the same producer refer to 40 CFR Part 152.30 for additional requirements);
- (3) distributed for use in an experimental use permit;
- (4) distributed for use under an emergency exemption;
- (5) or import is solely for the purpose of formulation or packaging for subsequent export provided certain requirements are met (see PR Notice 99-1, Exhibit 14-3).

Import of Pesticides That Are Exempt From FIFRA Regulations

Substances or mixtures of substances that are being put through laboratory, greenhouse or small scale field tests to determine pesticidal activity are substances with pesticidal characteristics and must enter the U.S. in accordance with statutory and regulatory requirements pursuant to Section 17(c) - **there is no exemption from FIFRA import requirements for pesticidal test substances.** Pesticides and pesticidal substances used in research and development are still pesticides and regulated by Section 17(c) and 19 CFR Part 12.110 through 12.117 (see Exhibit 14-5).

Substances are either regulated by FIFRA, TSCA or FFDCA. If the substance is characterized as a pesticidal chemical, then it is regulated under FIFRA. If the substance is characterized as a pharmaceutical chemical, then it is regulated under FFDCA. If the substance is neither pesticidal or pharmaceutical, then it is regulated under TSCA. Only TSCA exempts TSCA regulated R&D chemicals from the import requirements of the TSCA statute and regulations. FIFRA does not exempt pesticidal R&D chemicals from the import requirements for the Act and regulations.

Import of Registered Pesticides and Devices

Before pesticides or devices can be imported into the United States, the importer must submit a NOA of Pesticides and Devices, EPA Form 3540-1 (see Exhibit 14-4) prior to the arrival of the shipment in the United States. The EPA Regional office shall:

- < Complete Part II of the NOA, indicating the disposition to be made of the shipment of pesticides or devices upon its arrival in the United States.
- < Return the completed NOA to the importer or its agent.

Normally, an import broker will represent the importer in obtaining EPA and U.S. Customs clearance.

Upon the arrival of a shipment of pesticides or devices, the importer (or broker) shall present to the U.S. Customs at the port of entry the NOA completed by the EPA Regional office indicating the appropriate Customs action to be taken with respect to the shipment.

Regional Office

The Regional office supervisor/import coordinator and pesticide inspectors should maintain a cooperative working relationship with the U.S. Customs Service and customs brokers. This is vital to understanding the way each different Port of Entry conducts its business. Upon receipt of the NOA, the Regional office should review the NOA for completeness and determine whether to inspect and/or sample based on the following:

- < Pesticides/devices suspected of noncompliance (e.g., unregistered pesticides and/or unregistered establishment).
- < Pesticides/devices with a violative history (the Region may have knowledge of a violative product or company).

- < First-time import of a pesticide/device to the Region.
- < Pesticides/devices imported regularly with a good history of compliance (i.e., high volumes).

If a decision is made to inspect the imported pesticide/device, Part II of the NOA will indicate what action to take. The options are:

- < **Detention of the pesticides/devices by Customs for inspection by EPA.** The expenses associated with the detention must be borne by the importer. It is important that the inspection be conducted as soon as possible since the fate of the shipment is determined by the inspection. This type of inspection is likely to occur at the Port of Entry as the shipment is not usually released to the importer until compliance is determined by EPA. The shipment may have been picked up by the consignee under an Immediate Delivery entry (usually an electronic entry) (19 CFR Part 142.21-142.22; Exhibit 14-12). In such cases, the shipping company or the import broker should be requested to locate and hold the product for inspection.
- < **Release of the shipment of pesticides/devices under Bond.** In accordance with section 17(c) of FIFRA, EPA may instruct Customs to release a shipment of pesticides/devices under a Bond for the return of the imports to the custody of Customs. When this option is chosen the shipment is technically being detained because the pesticides/devices cannot be used or otherwise disposed of until EPA conducts an inspection and makes a determination. This type of inspection will take place at the consignee's facility and must proceed following normal protocol for establishment inspections. Whenever circumstances permit, EPA should consult with Customs personnel at the Port of Entry to ensure that the bond set by Customs [(see Exhibit 14-11) 19 CFR 113.61 and 113.62] is of an amount significant enough to compel the importer to hold the shipment for inspection. Circumstances such as prior knowledge of the quantity and/or estimated value of the shipment as well as the status of the cooperative working relationship between EPA and Customs personnel at the Port of Entry will dictate the feasibility of such a consultation. In special circumstances where concern exists that a bond may not stop distribution of the products, the EPA Regional office should consider issuing a Stop Sale, Use, or Removal Order (SSURO).

If the EPA Regional office instructs Customs to either detain the imported pesticides/devices, or to release the shipment under a bond, an EPA inspector must be prepared to conduct an inspection. Documentary Samples of labels and/or pesticides can be taken to determine compliance with FIFRA.

The location of detained pesticide import shipments is determined by the U.S. Customs Service and carried out by the import broker. The location will be a U.S. Customs licensed and bonded warehouse operated by private storage/warehouse company.

Customs

The U.S. Customs regulations governing the procedure for pesticide imports are located in 19 CFR Part 12 (Exhibit 14-10). Although these are helpful guidelines, these procedures are not standardized. Nothing can replace a cooperative working relationship with Customs and customs brokers, as each Port of Entry may follow a somewhat different protocol. Some Customs offices will not allow inspections to take place at the Port, sometimes even the bond placed on a shipment might have a different meaning depending on the Port. This makes it crucial that the Regional office and the inspectors maintain a close relationship with Customs to keep up with these various differences.

Inspections and Sampling

Imported pesticides/devices can be inspected at different Ports of Entry or other locations depending on how the shipment arrived in the United States and the U.S. Customs status of the shipment.

Upon arrival at the inspection site, the inspector must introduce himself/herself, present federal credentials (as all import inspections are conducted under section 8 and 9 of FIFRA), explain the purpose of the inspection and issue a Notice of Inspection (EPA Form 3540-2) with the reason for inspection. The Notice of Inspection must be issued to the person who has control of the product at the time of the inspection. The U.S. Customs Service never takes custody of the product during the importation/entry of the shipment. A Notice of Inspection is issued to the importer, import broker, bonded warehouse owner, or shipper of the import.

Import Sampling

Physical samples should be collected if EPA suspects that the pesticide product has been adulterated or suspects that the composition of the pesticide product is different from the Confidential Statement of Formula (CSF) in connection with the registration of the product. For all other suspected or observed violations, documentary samples are sufficient to demonstrate a violation of FIFRA and provide sufficient weight of evidence to instruct the U.S. Customs Service to refuse entry of the import shipment. Documentary samples will always include photographs of the label and labeling on the pesticide containers in the import shipment. There will never be any “bin labels” or other items to collect as documentary samples of the pesticide product.

The inspector must take the following steps when obtaining physical samples:

- < Issue a Receipt for Samples for any samples taken.

- < Submit the sample to the appropriate laboratory and ask the laboratory to expedite the analysis.
- < Inform the supervisor/import coordinator that a sample has been collected and sent for analysis.

Following a sample collection, and while waiting for chemical analysis or case review, the pesticide will have to be detained. The location where the pesticide is held must be determined by the import broker and U.S. Customs agent. The shipment must be kept intact until EPA makes a determination of compliance.

Inspection Without Sampling

When conducting an inspection without sampling, the inspector must complete the following steps:

- < Review the labeling for mandatory label requirements. Prior to inspection of detained shipments, a copy of the label should be obtained from the Product Manager (PM) in the Office of Pesticide Programs (OPP), or from the Pesticide Product Labeling System (PPLS) at:
<http://www.epa.gov/pesticides/pestlabels>
- < Check for collateral labeling such as books, pamphlets.
- < Check condition of the lot.

If a label or labeling violation is noted, the inspector must photograph or photocopy the label for documentary evidence (see Chapter 9 for more information on sampling procedures).

Regional Office Procedure After Inspection

Merchandise Complying With the Act

If the imported pesticide/device is found to be in compliance with the Act, the Regional office must notify the U.S. Customs Service that the shipment may be released to the consignee.

One way to standardize the way Regions notify Customs that the shipment may be released may be to “CC” the District Director of Customs at the Port of Entry on a “Release Notice” addressed to the importer of record. For purposes of expediting the notice, EPA Regional personnel should fax a copy of the release notice to their Customs staff counterpart at the Port of Entry. A Model Release Notice is included as Exhibit 14-7.

Merchandise Not Complying With the Act

If the imported pesticide/device is found to be in violation of the Act, the Regional office must refuse admission of the pesticides/devices into the country. Notification of this refusal must be made by EPA to the consignee. This procedure is consistent with the Customs Regulation in 19 CFR 12.117(b) (See Exhibit 14-9 for a Notice of Detention and Hearing). The consignee is given 20 days to submit written material, or at the option of the consignee, appear before EPA and introduce testimony to show cause why the shipment must not be destroyed or refused entry. If no hearing is requested or, after consideration of the evidence, it is still the opinion of EPA that the shipment is in

violation of FIFRA, the importer has 90 days from the date of receipt of the “Notice of Refusal of Admission” to export the violative products. One way to standardize the way Regions notify Customs that the shipment has been refused admission may be to “CC” the District Director of Customs at the Port of Entry on a “Notice of Refusal of Admission” addressed to the importer of record. For purposes of expediting the notice, EPA Regional personnel should fax a copy of the release notice to their Customs staff counterpart at the Port of Entry. A model “Notice of Refusal of Admission” is found at Exhibit 14-8. If this does not occur, the U.S. Customs Service in cooperation with EPA may oversee the destruction of the pesticides/devices; although this is done as last resort because of the expense to the U.S. Customs Service and the public.

Possible violations of FIFRA can include any of the unlawful acts described in sections 12(a)(1), 12(a)(2)(M), and 12(a)(2)(N) of FIFRA. These include but are not limited to, distribution of an unregistered pesticide, distribution of a misbranded or an adulterated pesticide, and failure to file reports required by the Act. Stop Sale Orders and Seizures under section 13 of FIFRA can be issued for imports suspected of being in violation of the Act. Note: there is always an importer of record for every import shipment, and it is this person who is held liable for any violations. Import brokers only act as agents of the importer of record and become jointly liable if a violative product is found to be distributed (imported) into the U.S.

A FIFRA import inspection checklist (Exhibit 14-6) will assist the inspector covering all the above items.

Exhibit 14-1

Environmental Protection Agency

§168.65

168.75 Procedures for exporting unregistered pesticides-purchaser acknowledgement statements.
 168.85 Other export requirements.

AUTHORITY: 7 U.S.C. 136-136y.

SOURCE: 54 FR 1125, Jan. 11, 1989.

Subpart A—General Provisions [Reserved]

Subpart B—Advertising

§168.22 Advertising of unregistered pesticides, unregistered uses of registered pesticides and FIFRA section 24(c) registrations.

(a) FIFRA sections 12(a)(1) (A) and (B) make it unlawful for any person to “offer for sale” any pesticide if it is unregistered, or if claims made for it as part of its distribution or sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA section 3. EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access.

(b) EPA regards it as unlawful for any person who distributes, sells, offers for sale, holds for sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver any pesticide, to place or sponsor advertisements which recommend or suggest the purchase or use of:

(1) Any pesticide for a use authorized under a FIFRA section 5 experimental use permit (EUP).

(2) Any pesticide for a use authorized under a FIFRA section 18 emergency exemption, except for advertisements that:

(i) Are placed in media which address primarily persons in the geographical area to which the exemption applies.

(ii) State the name and address of one or more retail dealers who stock the pesticide.

(iii) Contain a prominent notice of the limitations on use under the section 18 emergency exemption.

(3) Any pesticide for any use authorized only by a FIFRA section 24(c) special local need registration, unless the advertisement contains a prominent notice of the limitations on use under the section 24(c) registrations

(4) Any unregistered pesticide for any use unless the advertisement is one permitted by paragraph (b) (2) or (3) of this section.

(5) A registered pesticide product for an unregistered use, unless the advertisement is one permitted by paragraph (b) (2) or (3) of this section. However, as a matter of policy, the Agency will not regard as unlawful the advertisement of uses permitted by FIFRA section 2(ee) provided the product is not an antimicrobial pesticide targeted against human pathogens (see 51 FR 19174; May 28, 1986).

(c) For purposes of paragraph (b) of this section, a “prominent notice of the limitations on use” is one which sets forth the limitations on use in a manner reasonably likely to be understood by persons to whom the advertisement is addressed. For printed advertising, this criterion will be met by a legend in 6-point or larger type.

Subpart C [Reserved]

Subpart D—Export Policy and Procedures for Exporting Unregistered Pesticides

SOURCE: 58 FR 9085, Feb. 18, 1993, unless otherwise noted.

§168.65 Pesticide export label and labeling requirements.

(a) *General.* This section describes how EPA interprets and will enforce the requirements of FIFRA section 17(a)(1). Every exported pesticide, device, and active ingredient used in producing a pesticide (see § 152.3 of this chapter for the definition of “active ingredient” and “pesticide”) must bear a label or labeling which meets the requirements of FIFRA section 17(a)(1). This requirement applies to all such pesticides, devices, or active ingredients, regardless of whether the export is for commercial or research use. In the case of unregistered pesticides, including research substances which are being exported for testing, the labeling requirements of this section continue to apply independently of whether the exporter must submit a purchaser acknowledgement statement under FIFRA section 17(a)(2) as described at §168.75 of this

chapter. In addition, information which will satisfy FIFRA section 2(q)(1)(E), (G), and (H) and section 2(q)(2)(A) and (D) must appear in English and in the appropriate foreign languages, on the label or labeling as described in paragraph (b)(4) of this section. The required label and labeling statements may be met through either immediate container labels, accompanying supplemental labeling as described in paragraph (c) of this section, or a combination of the two.

(b) *Specific requirements.* The labels and labeling of any exported pesticides, devices, and active ingredients used in producing pesticides must meet the requirements regarding label and labeling content, correct representation, and understandability as stated in this paragraph.

(1) *Label contents.* The term *label* means the written, printed, or graphic matter on or attached to the immediate container of the pesticide, device, or active ingredient used in producing a pesticide. In the case that the immediate container is enclosed in an outer container or wrapper through which the label cannot be read, the label must also be on such outer container or wrapper. Except as provided in paragraph (c) of this section, the immediate container of the pesticide, device, or active ingredient used in producing a pesticide must bear a conspicuous and readable label which includes:

(i) *EPA pesticide producing establishment number.* The producing establishment registration number must be present but may appear anywhere on the label or immediate container in accordance with the establishment registration labeling requirements set forth in § 156.10(f) of this chapter.

(ii) *Warning or caution statements.* Warning or caution statements must appear on the label and must be adequate for the protection of persons handling the pesticide, device, or active ingredients including warnings regarding general toxicological hazards and environmental, physical, or chemical hazards. Warning and caution statements must appear in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. Where the U.S. warning or caution statement, as translated, is obviously inappropriate to protect residents of the importing country, (for example, where a statement calls for a gas mask meeting the

specification of the U.S. Bureau of Mines) an equivalent caution must be substituted.

(iii) *The statement “Not Registered for Use in the United States of America.”* The labels of all pesticides, devices, and active ingredients which are not registered for use in the United States under FIFRA section 3 must prominently display the following statement: “Not Registered for Use in the United States of America.” The statement must appear in English and in appropriate foreign languages, as described in paragraph (b)(4) of this section. It is permissible to append explanatory text which qualifies the statement by pointing out the reasons for the unregistered status. Examples of possible additional statements are “Not Registered for Use on...”, “No Longer Registered for Use...”, or “Not Registered... because...” Such additions must not be misleading or misrepresent the registration status of the pesticide. The statement “Not Registered For Use in the United States of America” must also be present.

(A) A pesticide is considered registered for the purposes of the section 17(a)(1) requirement only when:

(1) A label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(2) The formula of the exported product is the same as the formula of the U.S. registered product (within certified limits). In addition, a change in the color or fragrance of the export product will not affect the product’s registration status, as long as the following conditions are met:

(i) The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at § 180.1001, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA’s Policy Statement on Inert Ingredients in Pesticide Products, which can be obtained from the Office of Pesticide Programs public docket, Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.)

(ii) The change in fragrance must result

only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (§ 180.1001) and the chemical must not be a List 1 inert.

(iii) The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See “Food Fragrances in Pesticide Formulations,” EPA’s Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975 which can be obtained from the Office of Pesticide Programs public docket, Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.).

(iv) Any differences in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(3) No statements which appear on any of the product labels or labeling add new uses or claims or in any way contradict the approved FIFRA section 3 labeling. However, certain minor changes may be made to a product’s labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter.

(iv) *The ingredient statement.* The ingredient statement must appear on the label in English and in appropriate foreign languages (as described in paragraph (b)(4) of this section). If the English language description of the ingredients is easily identifiable and likely to be understood by the ordinary individual, the foreign language ingredient statement need not be included on the label. In the case of pesticide products, devices and active ingredients shipped solely for research and development purposes, it is permissible to use coded identification of ingredients on the label in order to protect confidentiality, in accordance with the requirements of §§ 168.75(c) and 168.85(a).

(v) *Identity of parties.* The name and address of the producer, registrant (if any), or the person for whom the pesticide was produced, must appear on the label.

(vi) *Weight or measure.* The net weight must appear on the label in either English or metric units.

(vii) *Additional warning for highly toxic pesticides.* If the pesticide, device or active

ingredient is highly toxic to humans, the skull and crossbones, the word “Poison”, and a statement of practical treatment must appear on the label. The word “Poison” and the statement of practical treatment shall be in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. The skull and crossbones may be in red or black. For criteria on what pesticides are highly toxic, see § 156.10(h) of this chapter.

(2) *Use classification statement.* In addition to the label contents described in paragraph (b)(1) of this section, the labeling must include a use classification statement, if a use classification has been assigned under a FIFRA section 3 registration. The use classification shall accurately describe the use classification applicable to the U.S. registered use of the pesticide, device or active ingredient (e.g., “Restricted Use Pesticide”). Summary statements describing the use classification, e.g., “For retail sale to and use only by Certified Applicators...”, or explaining what such terms mean are not required, but may be included if such statements do not result in false representation of the U.S. regulatory status of the pesticide. The use classification information may appear on the product label or on the labeling accompanying the pesticide product during shipment.

(3) *Misrepresentation.* The labeling shall not make false or misleading representations or represent the product as an imitation of other products.

(4) *Understandability.* The required statements must be expressed in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. To satisfy this section, certain information described in paragraph (b)(4)(i) of this section, which appears on the labeling of all exported pesticide products, devices and active ingredients must appear in English, in an acceptable language of the country of import as defined in paragraph (b)(4)(ii) of this section, and in an acceptable language of the country of final destination, if known or reasonably ascertainable by the exporter. When there are several official languages or dialects in a country, the language which is predominately spoken or written, or a language in which official government business is conducted, will be acceptable.

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(i) *Information required to be multilingual.* The following labeling information must be multilingual:

(A) The warning and caution statements.

(B) Where required, the statement “Not Registered for Use in the United States of America.”

(C) The ingredient statement.

(D) Where required in accordance with paragraph (b)(1)(vii) of this section, the word “Poison” and the statement of practical treatment in case of poisoning.

(ii) *Acceptable languages.* In all cases, English must be one of the languages used on the label or labeling. In addition, either the language which is used to conduct official government business, or the predominantly spoken or written language of the country of import must appear on the labeling. In each case where a country of final destination is known, the language which is used to conduct official government business or which is predominantly spoken in that country, if different from the language of the country of import, shall also appear on the labeling. In any case where English is predominantly spoken or written or is the language used to conduct official government business in a country, no other language need be included to meet the multiple language requirement of this paragraph.

(c) *Supplemental labeling.* A pesticide, device or active ingredient intended for export will not be considered in violation of the labeling requirements of FIFRA when the label and/or labeling requirements stated in paragraph (b) of this section are met by supplemental labeling. Supplemental labeling must be attached to the immediate product container or the shipping container of the pesticide, device or active ingredient at all times when it is shipped or held for shipment to meet export label requirements. Supplemental labeling must meet all of the label requirements in paragraph (b) of this section which are not met by the immediate product labels. Supplemental labeling will satisfy the labeling requirements of FIFRA only if the following conditions are met:

(1) *Applicability.* The use of supplemental labeling applies to any situation where the labeling requirements specified in this section are not met fully on the product label which is attached to the immediate product container. Any required label or labeling statement not

met on the immediate container may be met through supplemental labeling.

(2) *Labeling contents and relation to shipment.* If supplemental labeling is used to meet any of the labeling requirements of FIFRA section 17(a)(1), it must meet all of the requirements in paragraph (b) of this section which are not met by the label on the immediate product container. Thus, the supplemental labeling, together with the immediate product container label will meet all of the requirements of paragraph (b) of this section. Where used, supplemental labeling must be attached to or accompany the product shipping container of the pesticide, device, or active ingredient used in producing a pesticide at all times when shipped or held for shipment in the United States.

§168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statements.

This section describes how EPA interprets and will enforce requirements of FIFRA section 17(a)(2). Section 17(a)(2) provides that any person exporting a pesticide other than a pesticide registered for use under FIFRA section 3 or sold under FIFRA section 6(a)(1), shall obtain a statement signed by the foreign purchaser prior to export, acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States. Section 17(a)(2) requires that a copy of the statement be transmitted to an appropriate official of the government of the importing country.

(a) *Products subject to the requirement.* EPA will not consider an exporter of an unregistered pesticide to be in violation of FIFRA section 17(a)(2) if, prior to export of the pesticide, the exporter submits to EPA a statement signed by the foreign purchaser which affirms that the purchaser is aware that the pesticide is not registered for use in the United States and cannot be sold for use in the United States. The exporter must also include with the submission of the purchaser acknowledgment statement to EPA, a certification signed by the exporter affirming that the export did not occur until the statement signed by the foreign purchaser was obtained by the exporter. Except as provided in paragraph (b) of this section, all pesticide products produced for export which cannot be sold for use in the United States in the form that they are produced for export, are considered to

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be unregistered pesticides. This includes pesticides which are of a different formulation, including composition (except for variation within certified limits), or type of formulation, and pesticides which are packaged for use patterns for which they are not registered, which may be evidenced by package type or label use statements. This also includes unregistered products which are under development as pesticidal products and which are being exported for research testing.

(b) *Exceptions.* Under the specific circumstances discussed below, EPA will not treat a registered product which has been modified slightly for export purposes, as unregistered for the purposes of the purchaser acknowledgment statement requirement. Any changes to the registered product for export purposes must be documented in accordance with the record-keeping requirements at § 169.2 of this chapter and this policy.

(1) *Labeling on Immediate Product.* EPA will not treat as unregistered for the purposes of section 17(a)(2), a registered pesticide product which cannot be sold or distributed for use in the United States because its immediate product container does not bear a label approved under a FIFRA section 3 registration, but which could be sold or distributed in the United States with the approved label attached to the immediate product container, provided that the label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(2) *Packaging.* (i) Certain changes may be made to a product's labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter and this policy. These changes include any changes in package size and label net contents, provided no change in use directions or requirement for child-resistant packaging would be necessary for the product to be registered for use in the United States. For example, if child-resistant packaging is required for a particular pesticide product in the United States, and the product will be exported without child-resistant packaging, the product would be considered unregistered and therefore subject to all the requirements of FIFRA section 17(a), as described in § 168.75 of this

chapter including the requirement for a purchaser acknowledgment statement.

(ii) If an exporter needed to repackage a product in a size to meet a foreign purchaser's specifications, that modification would not affect the registration status of the export product. Other modifications to the label used for export purposes which will not affect the export product's registration status are: the use of metric units for net contents, dosages, and other numeric expressions; the use of a different format for the label, provided that the information does not contradict the U.S. label; revision of nonmandatory U.S. label statements, consistent with 40 CFR part 156, including additions or changes required by other Federal statutes or regulations; a change of the name or address of the registrant, except for a change resulting from transfer of ownership, which requires that a registrant keep his name and address current with the Agency; and any correction of typographical or printing errors that appeared on the U.S. labeling. (See § 152.46(b)).

(3) *Labeling statements.* The following statements which appear on any of the product labels or labeling will not affect the status of the product, provided that they do not contradict the approved FIFRA section 3 labeling:

(i) It is permissible to add explanatory language which accurately explains the meaning of a use classification. For example, the statement "restricted use pesticide" may be expanded to read: "Restricted in the United States of America to use by certified applicators" or "Restricted Use Pesticide. In The United States this product is restricted to use by applicators determined by each state to be competent in pesticide application and the human health and environmental consequences of misuse." If the explanatory language falsely represents or is misleading regarding the U.S. use classification, the product will be considered misbranded. In addition, a use classification can only be listed if one has been assigned pursuant to the U.S. registration.

(ii) An exporter who is also the manufacturer of a U.S. registered pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. (Pesticide use patterns are

listed in appendix A to 40 CFR part 158—Data Requirements for Registration: Use Pattern Index. The general pesticide use patterns are: terrestrial food crop and terrestrial nonfood crop; greenhouse food crop and greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop; indoor use; and forestry use.) Adding new uses to the label which change the use pattern, such as changes from non-food to food use, outdoor to indoor use, or terrestrial to aquatic use, render the product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed use, a tolerance must already be established for the use of that pesticide in or on that commodity.

(4) *Composition.* EPA will not treat a registered product as unregistered for the purposes of the purchaser acknowledgment statement requirement under the following specific circumstances:

(i) The formula of the exported product is within certified limits of the formula of the U.S. registered product.

(ii) An exporter, who is also the manufacturer of a U.S. registered pesticide, may decrease the percentage of the active ingredient(s) of that product by adding a List 4 inert ingredient, without causing the product to be treated as “unregistered” and triggering the requirement to obtain a purchaser acknowledgment statement as a condition for export. In EPA’s Policy Statement on Inert Ingredients in Pesticide Products, EPA included inert ingredients on List 4—a list of inert ingredients posing minimal hazard or risk—if the inert ingredients were generally regarded as innocuous. The provisions of this paragraph do not apply to those pesticide products intended for public health uses which are required or conditionally required to submit efficacy data pursuant to § 158.640 of this chapter. Any differences in formula or composition caused by adding a List 4 inert must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(iii) A change in the color or fragrance of the export product will not affect the product’s registration status as long as the following conditions are met. The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at § 180.1001, and the dye must not be a List 1 inert. (List 1 inerts

are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA’s Policy Statement on Inert Ingredients in Pesticide Products. The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (§ 180.1001) and the chemical must not be a List 1 inert. The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See “Food Fragrances in Pesticide Formulations,” EPA’s Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975.) Any difference in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(5) *Research and development products.* An unregistered pesticide product exported only for research and development purposes is subject to the notification requirements of this section, unless its use fits within the criteria described in this paragraph.

(i) An unregistered pesticide product exported solely for research and development purposes will not be considered to be in violation of the notification requirements if the export of the research and development product:

(A) Would not involve land uses of more than 10 acres (4.05 hectares), or be used on or affect food or feed crops which are intended for consumption.

(B) Would not involve aquatic uses of more than 1 acre (0.405 hectares), or any aquatic uses which involve water used for irrigation, drinking or recreation, or be used on or affect plants or animals taken for food or feed from such waters.

(C) Would not involve tests on animals intended for food or feed

(ii) Shipments to different purchasers, to different countries of final destination, or which occur more than a calendar year apart will be evaluated separately. When determining whether total shipments exceed the criteria described in this paragraph, EPA will evaluate the total amount of shipments by a single exporter during a calendar year for use in a particular country.

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(iii) An exporter bears the burden of demonstrating that the product meets these criteria before

the research product is shipped. This may be met by documenting before the product is shipped and maintaining records for the time period required by § 169.2(h) of this chapter from the date of the last shipment relevant to such records. The records to be maintained consist of:

(A) The identity of the purchaser and country of intended use of the research product.

(B) The amount shipped.

(C) The intended research use by the purchaser, including the type of application site, rate of application, and measures taken for protection of humans from direct or dietary exposure.

(c) *Procedures.* An exporter of an unregistered pesticide product must submit a purchaser acknowledgment statement to EPA containing the information stated in paragraph (c)(1) of this section, and a statement signed by the exporter certifying that the exportation did not occur until the signed acknowledgment statement had been obtained from the purchaser. If the foreign purchaser signs a purchaser acknowledgment statement in their own language, it must be accompanied by an English translation when it is submitted to EPA by the exporter. These statements shall be submitted in accordance with one of the two options for submission described in paragraph (c)(2) of this section.

(1) *Contents of the purchaser acknowledgment statements.* The purchaser acknowledgment statement must include the following information in a format that is clearly understandable:

(i) Name, address, and EPA identification number, if applicable, of the exporter.

(ii) Name and address of the foreign purchaser.

(iii) Identity of the product and the active ingredient(s), including:

(A) The Chemical Abstract Services (CAS) Registry number for each active ingredient.

(B) The chemical nomenclature for each active ingredient as used by the International Union of Pure and Applied Chemists (IUPAC).

(C) Other known chemical or common names; or if the export involves a research product, a code name or identification number that can be used by EPA to identify the product from the exporter's records. If a code name or

identification number is used, additional information must be attached to the certification statement submitted with the purchaser acknowledgment statement which will enable EPA to identify the product. This attached information may be claimed as confidential, and EPA will not forward this information with the purchaser acknowledgment statement to foreign governments.

(iv) If known or reasonably ascertainable, the country or countries of final destination of the export shipment, i.e., where the exported pesticide is intended to be used, if different from the country of the foreign purchaser's address.

(v) A statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.

(vi) The signature of the foreign purchaser.

(vii) The date of the foreign purchaser's signature.

(2) *Reporting options.* At the discretion of the exporter, the requirements of paragraph (c)(1) of this section may be met on a per-shipment or annual basis, as stated in paragraphs (c)(2)(i) and (c)(2)(ii) of this section. If the procedures in paragraph (c)(2)(ii) of this section are not followed, EPA will consider paragraph (c)(2)(i) of this section, requiring pershipment purchaser acknowledgment statements, to be applicable in full. Where paragraph (c)(2)(i) of this section is applicable, each shipment which does not meet the requirements of that paragraph will be considered to be a separate violation of FIFRA.

(i) *Per-shipment purchaser acknowledgment statement.* Unless the exporter chooses to follow the procedures described in paragraph (c)(2)(ii) of this section for the annual reporting procedures, the exporter must obtain and submit to EPA, a signed purchaser acknowledgment statement prior to each shipment of an unregistered pesticide according to the following procedures:

(A) Prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgment statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly

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completed, signed, and dated acknowledgment statement.

(B) The exporter must obtain, prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgment statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgment statement was received. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgment statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgment statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgment statement, or by the date of export, whichever occurs first. This information must be transmitted to the following address:

U.S. Environmental Protection Agency, Office of Pesticide Programs, (H-7501C), 401 M Street, SW, Washington, DC 20460, Attention: Purchaser Acknowledgment Statement.

(ii) *Annual reporting procedures.* Unless the exporter chooses to follow the per-shipment reporting option described in paragraph (c)(2)(i) of this section, the exporter must follow the procedures for annual summary reporting which include the requirement of a purchaser acknowledgment statement for the first shipment each calendar year of an unregistered pesticide product to a particular purchaser, and an annual summary of shipments to that 10:15 Jul 25, purchaser. The annual summary reporting procedures are as follows:

(A) Prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the

pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated purchaser acknowledgement statement.

(B) The exporter must obtain, prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgement statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received, indicating that this statement is for the first shipment to a particular purchaser in a specific country for that calendar year, and that the exporter will meet all the purchaser acknowledgement statement requirements as described in this paragraph (c)(2)(ii) of this section. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement statement, or by the date of export, whichever occurs first. This information must be transmitted to the following address:

U.S. Environmental Protection Agency, Office of Pesticide Programs, (H-7501C), 401 M Street, SW, Washington, DC 20460, Attention: Purchaser Acknowledgement Statement.

(E) The exporter, who has chosen to comply with the requirements of this paragraph instead of providing pershipment purchaser acknowledgement statements in accordance with paragraph (c)(2)(i) of this section, must submit an annual summary report to EPA. An annual summary report is required for each unregistered pesticide exported within the preceding calendar year. The report must be in

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writing, signed by the exporter, and include the following information:

(1) Name, address, and EPA identification number if applicable, of the exporter.

(2) Name and address of the foreign purchaser, and the date the purchaser acknowledgment statement, submitted to EPA during the previous calendar year, was signed by the purchaser.

(3) The identity of the product and the active ingredients, including: the Chemical Abstract Services (CAS) registry number for each active ingredient, the chemical nomenclature for each active ingredient used by the International Union of Pure and Applied Chemists (IUPAC), and other known chemical or common names, or if the export involves a research product, the code name or identification number that can be used by EPA to identify the product from the exporter's records.

(4) The dates of each shipment of the pesticide exported to the foreign purchaser during that calendar year.

(5) If known, or reasonably ascertainable, the country or countries of final destination of the export shipments, i.e., where the exported pesticide was intended to be used, if different from the foreign purchaser's address.

(F) The exporter shall submit the annual summary no later than March 1st of the following calendar year. The annual summary shall be sent to the following address:

U.S. Environmental Protection Agency, Office of Pesticide Programs, H-7501C, 401 M Street, SW., Washington, DC 20460, Attention: Annual Summary of Exports.

(iii) *Confidentiality claims.* Persons submitting the information specified in 8010 the purchaser acknowledgment statement may assert a claim of business confidentiality by marking the information claimed confidential as "FIFRA Confidential Business Information." Information so claimed will not be disclosed, with the exception of disclosure to the foreign governments, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136(h), and this policy statement. If such claim is not asserted, EPA may disclose the information to the public without providing further notice prior to disclosure or an opportunity to object. Notwithstanding any claim of confidentiality, the purchaser acknowledgment statement will continue to be

forwarded to the appropriate foreign government officials in its entirety, as required by section 17(a)(2).

(3) *Recordkeeping.* Except as specifically stated, the requirement to retain records under part 169 of this chapter applies to all pesticide producers, regardless of whether a particular product is intended for export. All records shall be maintained in accordance with the time period required by § 169.2(h) of this chapter. Producers must also maintain certain records pertaining to pesticide products intended for export. In addition to the requirement that a copy of the purchaser acknowledgment statement be kept, as stated at § 169.2(h)(3) of this chapter, the following records must be maintained:

(i) Copies of the instructions provided to foreign purchasers in accordance with paragraphs (c)(2)(i)(A) and (c)(2)(ii)(A) of this section.

(ii) Copies of signed purchaser acknowledgment statements obtained according to paragraphs (c)(2)(i)(B) and (c)(2)(ii)(B) of this section.

(iii) Copies of the certification from the exporter; and copies of any accompanying information regarding the identity of coded R&D products.

(d) *Agency transmission of purchaser acknowledgment statements.* EPA will transmit a copy of each purchaser acknowledgment statement to the appropriate government official in each of the intended destination countries. After receipt of the Annual Summary the following calendar year, EPA will also transmit a copy of that document to the appropriate government official in each of the intended destination countries. In the case that no Annual Summary has been received within 30 days of the date at which such summary is required to be submitted, EPA will send written notification to the appropriate government official indicating that no summary was submitted, and may also take enforcement action against the exporter.

§ 168.85 Other export requirements.

This section describes other requirements found in regulations that apply to exporters of pesticides, devices, and active ingredients used in producing a pesticide.

(a) *Recordkeeping and inspection.* Exporters of pesticides, devices and active ingredients

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must keep records and permit inspections of those records in accordance with part 169 of this chapter. Exporters must keep records of the product labeling used, including the EPA registered labeling, any foreign labeling on or attached to the product when shipped, and, as applicable, any supplemental labeling used. Producers of pesticides for export shall maintain these records in a manner that shows exactly which labels and labeling accompanied each shipment of a pesticide product to a foreign country. As stated at § 168.75(c), when research product identity information appears on the labeling in an encoded manner, information translating the code shall be maintained in records. These records shall be maintained for the time period required by § 169.2(h) of this chapter following the last export of such pesticides. All records required by part 169 of this chapter shall be made available for inspection and copying by EPA or its duly authorized representatives.

(b) *Pesticide production establishment requirements.* Exporters of pesticides, devices, and active ingredients must submit annual reports to EPA in accordance with part 167 of this chapter, concerning those products that are exported. All products required to be labeled “Not Registered for Use in the United States of America” must be reported as unregistered production regardless of whether a purchaser acknowledgment statement is required.

Exhibit 14-2: FIFRA Export Inspection Checklist

FIFRA EXPORT INSPECTION CHECKLIST

Company _____ Est. No. _____

Address _____ Inspection Date _____

Inspector's Name and Phone Number _____

Product Name and (EPA Reg #) _____

Part I - Documentation Obtained YES/NO/Exhibit #

1) Are Section 7 Production Reports (#3540-16) included for this product for each targeted calendar year? [If reporting discrepancies were found, not in "Comments" section on page 2 of this form.] _____

2) Is the Confidential Statement of Formula or chemical formula included for this product? _____

3) Are production specifications/directions of the foreign purchaser included for this product? _____

If not, is statement from the appropriate company official as to why these records are not maintained by the facility? _____
 Is the actual location of the records known and included? _____

4) Are label(s)/supplemental labeling included for this product for each country to which it was exported? _____

No. of Countries ____ No. of labels _____

5) If product labels/labeling were not available, are bin labels included for this product? _____

Is an affidavit statement from the responsible company official included certifying that the labels/labeling or bin labels/labeling collected are identical to those used on exported product(s)? _____

Is photographic evidence of the product that was packaged, labeled and released for shipment at the time of the inspection included? _____

6) If labels were not available for inspection, is affidavit statement from the appropriate company official included as to why labels were not maintained by the facility? Is the actual location of the labels known and included? _____

7) Are foreign purchaser acknowledgment statements, as required by section 17(a)(2), included for the first shipment each year of a particular product to a particular purchaser for each importing country? _____

If not, is an affidavit statement included? _____

8) If the unregistered product was claimed to be “substantially similar” to an EPA registered product, is an affidavit statement included from a responsible company official specifically documenting such claims including the registered product name, EPA registration number, and rationale for such claims? _____

9) If the unregistered product was claimed to be a “research & development” or “experimental” pesticide, is an affidavit included from the responsible company official specifically describing the basis for such claims? _____

10) OPTIONAL If the unregistered product is claimed “substantially similar” to an EPA registered product, is a copy of the label for the registered product and Confidential Statement of Formula for the registered product included? _____

11) Is evidence of exported shipments included that clearly shows the product name, date(s) of each shipment, amounts of each shipment, and country of destination for each shipment? (This can include Bills of Lading, Invoices, and List of Consignees.) _____

12) Is evidence included that clearly shows the company responsible fore the product and its export? Is evidence included that clearly describes past and present corporate relationships, such as, mergers, takeovers and/or other corporate transactions/agreements? _____

13) Was information included for this product for all time periods requested? _____

2000 __ 2001 __ 2002 __ 2003 __

COMMENTS:

Part II - Labeling Requirements and Review

Does the label/Labeling for this exported product bear the following information? Attach a separate Part II sheet for each product label and foreign destination.

Product Name: _____ Foreign Destination: _____

	<u>Yes</u>	<u>No</u>
1. EPA Establishment Number?	_____	_____
2. Ingredient Statement?	_____	_____
3. Name/address of producer/registrant?	_____	_____
4. Statement of net weight or measure?	_____	_____
5. Use Classification statement? (Restricted Use or General Use Pesticide)	_____	_____
6. Precautionary statements? (Warning and caution statements)	_____	_____
7. If highly toxic, are "skull & crossbones", the word Poison and statement of practical treatment shown?	_____	_____
8. For unregistered products, does label bear the statement "Not Registered for Use in the United States of America"?	_____	_____
9. If the predominant language of the importing country is not English, are #'s 2, 6, 7, and 8 above also expressed in the language of the importing country? (Note that this information is required on both <u>registered and unregistered</u> products.)	_____	_____

Label Comments

Exhibit 14-3: Pesticide Registration (PR) Notice 99-1

March 1, 1999

Notice to Manufacturers, Producers, Formulators, Registrants and Importers of Pesticide Products

ATTENTION: Persons Responsible for the Importation of Pesticide Products
SUBJECT: Import of Unregistered Pesticides Intended for Export

I. SUMMARY

This Pesticide Registration (PR) notice clarifies EPA's interpretation of the scope of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 17 (a)(1), as it relates to the import of unregistered pesticides, devices or active ingredients used in producing a pesticide when the importation is solely for the purpose of formulation or packaging for subsequent export. Under the interpretation provided in this PR notice, such pesticides do not require registration under FIFRA, as long as they comply with the provisions outlined below. This interpretation is effective immediately.

In general, unregistered pesticides and unregistered active ingredients are not permitted to be imported. However, if a pesticide or unregistered active ingredient is being imported for the sole purpose of meeting the specifications of a foreign purchaser, such an import is permitted. The Agency interprets Section 17(a)(1) to allow the importation of unregistered pesticides or unregistered active ingredients used in producing a pesticide, provided the ultimate pesticide is produced for export only according to the specifications of the foreign purchaser. This policy does not authorize the importation of unregistered pesticide for the purpose of producing a U.S. registered product, even if part or all of that production is intended for export.

II. BACKGROUND

The Agency has received requests from a number of companies to allow importation of unregistered pesticidal active ingredients for the purpose of allowing reformulation into a pesticide intended to be exported. The requesters have essentially asked the Agency to interpret section 17(a) of FIFRA in a way that would exempt such importation from the requirements of FIFRA. That section provides in part that "no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of [FIFRA] when prepared or packed according to the specifications or directions of the foreign purchaser," provided the producers of such pesticides, devices, or active ingredients used in producing pesticides comply with various specified provisions of FIFRA sections 2, 7 and 8.

III. CLARIFICATION OF SCOPE OF SECTION 17**A. Conditions Permitting Import**

Having considered this issue, EPA believes there are certain circumstances under which unregistered pesticides and/or active ingredients may be imported into this country consistent with section 17. Specifically, EPA will consider importation of an unregistered pesticide or active ingredient into this country to be a lawful act under FIFRA if all of the following conditions apply:

1. The foreign producing establishment is registered under FIFRA Section 7 and is compliant with Section 7 reporting requirements.
2. Importation of the unregistered pesticide or active ingredient complies with all applicable regulations and section 17 of FIFRA (including presentation of an EPA authorized Notice of Arrival which specifies the quantities to be exported to Customs upon entry into the U.S.).
3. The shipment otherwise complies with all applicable Customs laws and regulations.
4. Upon lawful release by Customs, the imported unregistered pesticide or active ingredient is transported directly to a registered pesticide establishment. The owner of such establishment shall be responsible for filing an appropriate report under FIFRA section 7 concerning such imported pesticide or active ingredient which indicates the relevant activity, such as reformulation, relabeling or distribution.
5. Section 17(a) allows distribution (and importation) of an unregistered pesticide or active ingredient only if the pesticide or active ingredient are intended solely for export and have been prepared or packaged according to the specifications of the foreign purchaser. EPA interprets this to mean that the importation (and any subsequent movement) may occur only after a foreign purchaser has been identified and has provided the specifications for the exported product.
6. After the final product for export is formulated and packaged, any distribution or shipment of the product must be solely for the purpose of facilitating export of the product (i.e., all movement of the product must be directly related to exporting the product, such as shipment to a warehouse awaiting export, dock or broker).
7. The unregistered pesticide or active ingredient, and each person with any obligation under FIFRA section 2, 7, or 8 with respect to the unregistered pesticide or active ingredient, are at all times in compliance with all the applicable provisions of FIFRA identified in 17(a)(1).
8. The export of any unregistered pesticide or active ingredient complies with the purchaser acknowledgment requirements of 17(a)(2) of FIFRA.
9. The importer can demonstrate that, ultimately, all of the product has been exported, or is being held pending export.

B. Conditions after importation

EPA will consider any shipment or distribution after the original importation to a registered facility in the United States to be permissible under FIFRA (including section 17(a)) under the following conditions:

1. The shipment is either in compliance with 40 CFR 152.30 (a) (the shipment is between registered establishments owned or operated by the same producer) or,
2. The shipment is distributed only to facilitate export (the pesticide or active ingredient has been prepared or packaged according to the specifications of an identified foreign purchaser).

If any other shipments or distributions of an unregistered pesticide or active ingredient are made in the United States after the initial importation, the shipper is advised to have evidence indicating that the shipment conforms to the conditions outlined above. By way of example, such evidence could include an identification of the foreign purchaser, an explanation of why the shipment or distribution is necessary to facilitate legal export of a product under section 17(a) of FIFRA. Failure to produce such evidence could result in otherwise unnecessary stopping of the shipment, and/or a violation of FIFRA for selling or distributing an unregistered pesticide outside this limited exemption.

IV. FOR FURTHER INFORMATION

Any questions should be directed to: Cathleen M. Barnes, Government and International Services Branch, Field and External Affairs Division (7501C), Office of Pesticide Programs, USEPA, 401 M Street, S.W., Washington D.C., 20460, phone:703-305-7101, fax:703-308-1850, e-mail: barnes.cathleen@epa.gov.

Marcia E. Mulkey
Director, Office of Pesticide Programs

Exhibit 14-4: Notice of Arrival of Pesticides and Devices (EPA Form 3540-1)

		United States Environmental Protection Agency Washington, DC 20460 Notice of Arrival of Pesticides and Devices		Send Completed Form to Appropriate Regional Office Listed on the Reverse of this Form.		Form Approved OMB No. 2070-0020	
Note: Read Instructions on reverse before completing form.							
Part I: To Be Completed by Importer or Agent							
1. Name and Complete Address of Broker or Agent				2. Name and Complete Address of Importer or Consignee			
<input type="checkbox"/> Return Form to this Address				<input type="checkbox"/> Return Form to this Address			
3. Name and Address of Shipper				4. EPA Registration Number		5. EPA Producer Establishment No.	
				6. Brand name of Product			
7. Major Active Ingredients and Percentage of Each							
8. Unit Size		9. Quantity		10. Total Net Weight		11. Country of Origin	
12. Port of Entry				13. Carrier			
14. Entry Number			15. Entry Date		16. I assert that information constituting Confidential Business Information is shown in the above blocks numbered: (Note: Blocks 4, 5, 6, 7 are not entitled to CBI treatment—see Instructions)		
17. Location of Goods for Examination after Importation							
18. Remarks							
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.							
19. Printed Name of Importer or Agent			Telephone Number		20. Signature of Importer or Agent		Date Signed
Part II: To Be Completed by U.S. Environmental Protection Agency							
Action to be taken by U.S. Customs Service							
<input type="checkbox"/> Release Shipment		<input type="checkbox"/> Detain for Inspection		<input type="checkbox"/> Release shipment to consignee under bond. Shipment must be held intact pending inspection.			
<input type="checkbox"/> Other (Specify)							
Remarks							
Signature and Title of EPA Official						Date	
Part III: To Be Completed by U.S. Customs Service							
The information shown in Part I was compared with the entry papers for this shipment and no discrepancies were noted. The shipment was handled as instructed by EPA in Part II. Any deviations should be brought to the attention of EPA before releasing shipment and should also be noted in "Remarks."							
Remarks							
Signature of District Director of Customs						Date	

Exhibit 14-5

§12.110

19 CFR Ch. I (4–1–01 Edition)

PESTICIDES AND DEVICES

§12.110 Definitions.

Except as otherwise provided below, the terms used in §§ 12.111 through 12.117 shall have the meanings set forth for those terms in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 *et seq.*), hereinafter referred to as “the Act.” The term *Administrator* shall mean the Administrator of the Environmental Protection Agency.

[T.D. 75–194, 40 FR 32321, Aug. 1, 1975]

§12.111 Registration.

All imported pesticides are required to be registered under the provisions of section 3 of the Act, and under the regulations (40 CFR 162.10) promulgated thereunder by the Administrator before being permitted entry into the United States. Devices, although not required to be registered, must not bear any statement, design, or graphic representation that is false or misleading in any particular.

[T.D. 75–194, 40 FR 32321, Aug. 1, 1975]

§12.112 Notice of arrival of pesticides and devices.

(a) *General.* An importer desiring to import pesticides or devices into the United States shall submit to the Administrator a Notice of Arrival of Pesticides and Devices (Environmental Protection Agency Form 3540–1), hereinafter referred to as a Notice of Arrival, prior to the arrival of the shipment in the United States. The Administrator shall complete the Notice of Arrival, indicating the disposition to be made of the shipment of pesticides or devices upon its arrival in the United States, and shall return the completed Notice of Arrival to the importer or his agent.

(b) *Chemicals imported for use other than as pesticides.* Chemicals which can be used as pesticides but which are not imported for such use and are not shown on the Abbreviated List of Pesticides compiled by the Environmental Protection Agency, may be entered without the submission of the Notice of Arrival.

[T.D. 75–194, 40 FR 32321, Aug. 1, 1975]

§12.113 Arrival of shipment.

(a) *Notice of arrival presented.* Upon the arrival of a shipment of pesticides or devices, the importer or his agent shall present to the director of the port of entry the Notice of Arrival completed by the Administrator and indicating the Customs action to be taken with respect to the shipment. The port director shall compare entry documents for the shipment of pesticides or devices with the Notice of Arrival and notify the Administrator of any discrepancies.

(b) *Notice of arrival not presented.* When a shipment of pesticides or devices arrives in the United States without the presentation by the importer or his agent of the Notice of Arrival completed by the Administrator, the shipment shall be detained by the director of the importer’s risk and expense until the completed Notice of Arrival is presented or until other disposition is ordered by the Administrator, but not to exceed a period of 30 days, or such extended period, not in excess of 30 additional days, as the port director for good cause may specially authorize. An application of the importer or his agent requesting an extension of the initial 30-day period shall be filed with the director of the port of entry.

(c) *Disposition of pesticides or devices remaining under detention.* A shipment that remains detained or undisposed of due to failure of presentation of a completed Notice of Arrival or nonreceipt of an order of the Administrator as to its disposition shall be treated as a prohibited importation. The port director shall cause the destruction of any such shipment not exported by the consignee within 90 days after the expiration of the detention period specified or authorized pursuant to § 12.113(b).

[T.D. 75–194, 40 FR 32322, Aug. 1, 1975]

§12.114 Release or refusal of delivery.

If the completed Notice of Arrival directs the port director to release the shipment of pesticides or devices, the shipment shall be released to the consignee. If the completed Notice of Arrival directs the port director to refuse delivery of the shipment, the shipment shall be refused delivery and treated as a prohibited importation. The port director shall cause the destruction of any shipment refused delivery and not exported by the consignee within 90 days after notice of such refusal of delivery. [T.D. 75–194, 40 FR 32322, Aug. 1, 1975]

§12.115 Release under bond.

If the completed Notice of Arrival so directs, a shipment of pesticides or devices shall be detained at the importer's expense by the port director pending an examination by the Administrator to determine whether the shipment complies with the requirements of the Act. However, a shipment detained for examination may be released to the consignee prior to a determination] by the Administrator provided a bond is furnished on Customs Form 301, containing the bond conditions set forth in § 113.62 of this chapter, for the return of the merchandise to Customs custody. The bond shall be in an amount deemed appropriate by the port director. When a shipment of pesticides or devices is released to the consignee under bond, the shipment shall not be used or otherwise disposed of until the determination is made by the Administrator.

[T.D. 75-194, 40 FR 32322, Aug. 1, 1975, as amended by T.D. 84-213, 49 FR 41168, Oct. 19, 1984]

§ 12.116 Samples.

Upon the request of the Administrator, either on the completed Notice of Arrival or otherwise, the port director shall deliver to the Administrator samples of the imported pesticides or devices, together with all accompanying labels, circulars, and advertising matter pertaining to such merchandise. The port director shall notify the consignee, in writing, that the samples of imported pesticides or devices, together with all accompanying labels, circulars, and advertising matter pertaining to such merchandise have been delivered to the Administrator.

[T.D. 75-194, 40 FR 32322, Aug. 1, 1975]

§ 12.117 Procedure after examination.

(a) *Merchandise complying with the Act.* If, upon examination or analysis of a sample from a shipment of pesticides or devices, the sample is found to be in compliance with the Act, the Administrator shall notify the port director that the shipment may be released to the consignee.
 (b) *Merchandise not complying with the Act.* If, upon examination or analysis of a sample from a shipment of pesticides or devices, the sample is found to be in violation of the Act, the consignee shall be notified promptly by the Administrator of the nature of the violation and be given a reasonable time, not to

exceed 20 days, to submit written material of, at his option, to appear before the Administrator and introduce testimony to show cause why the shipment should not be destroyed or refused entry. If after consideration of all the evidence presented, it is still the opinion of the Administrator that the merchandise is in violation of the Act, the Administrator shall notify the port director of this opinion and the port director shall either (1) refuse delivery to the consignee, or (2) if the shipment has been released to the consignee under bond, demand redelivery of the shipment under the terms of the bond. If the merchandise is not redelivered within 30 days after the date of demand by the port director, the port director shall issue a demand for liquidated damages in the full amount of the bond, or if a continuous bond is used, the amount that would have been taken under a single entry bond. The port director shall cause the destruction of any merchandise refused delivery to the consignee or redelivered by the consignee pursuant to a demand therefore, and not exported by the consignee within 90 days after notice of such refusal of delivery or within 90 days after such redelivery, as applicable.

Exhibit 14-6: FIFRA Import Inspection Checklist

* For use after the Regional Office import coordinator has determined to inspect a shipment and has setup a location for the shipment to be inspected.

Inspector's Name/Number _____ / _____

1) Location of shipment to be inspected _____

The following information can be obtained from the Notice of Arrival (NOA) Form 3540-1 or the papers accompanying the shipment. If a NOA has been completed it can be obtained from the Regional Office import coordinator.

2) Importer/Consignee _____ 3) Shipper _____
Address _____ Address _____

4) Broker/Agent _____ 5) Carrier _____
Address _____

6) EPA Registration Number _____ 7) EPA Establishment Number _____

8) Brand Name of Product _____

9) Major Active Ingredients and Percentage of Each _____

10) Unit size _____ 11) Quantity _____ 12) Total Net Weight _____

Inspection Procedures:

Check if Applicable

13) Obtain a copy of the EPA approved label from the EPA Regional Office _____

14) Prior to inspecting a shipment of pesticides and/or devices, request from the importer/consignee or customs broker copies of the product label and, if

- available other advertisements accompanying the sale of the product. _____
- 15) Issue NOI and show federal credentials to appropriate person. _____
- 16) Collect photographs of the label(s) and labeling on the container(s) of the import shipment. Review for conformity with label requirements (Procedures for conducting label reviews can be found in Chapter 7 of the Pesticide Inspection Manual). _____
- 17) Collect all records regarding import of shipment, such as:
 - Copies of NOA _____
 - Foreign invoices _____
 - Shipping records (i.e., manifests or waybills) _____
- 18) Review other label information in books, pamphlets, circulars, and displays - if applicable. _____
- 19) Document the physical condition of the lot. _____
- 20) Photograph containers and the labels thereon. _____

If physical samples are taken, follow these additional steps:

- 21) Note on Receipt for Samples that it is an import sample, and identify the sample with "IMP" preceding the sample number. _____
- 22) Request that the laboratory expedite the analysis _____
- 23) Ensure that the product container is properly resealed. _____
- 24) Notify the Regional Office that samples have been collected. _____

Exhibit 14-8: Model Notice of Refusal of Admission

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Name, President

Company Name

Company Address

Re: NOTICE OF REFUSAL OF ADMISSION
Entry Number (Assigned by Customs) (Product Name)

Dear (President's Name):

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, or the Act), as amended, 7 U.S.C. 136 et al., the United States Environmental Protection Agency has examined samples or other evidence with respect to the following shipment and has granted to you an opportunity for a hearing.

Sample Number (if an inspection has been conducted):

Product Name:

Shipper/Manufacturer: Consignee:

Entry Number: Date of Importation: Port of Entry:

It appears that the product is not in compliance with the Act and is subject to refusal of admission due to the following violations (Describe violations).

The Agency hereby notifies you that your merchandise has been refused admission. You must export this merchandise, under supervision of the U.S. Customs Service, within ninety (90) calendar days from the date of this Notice (or within such time as otherwise specified by EPA) or within such additional time as the District Director of Customs specifies. Failure to do so may result in either the destruction of the merchandise as authorized by the Act, or, if the shipment has been released to you under bond, in any action necessary to enforce the terms of said bond.

Sincerely,
/s/
(Name and Title)

Exhibit 14-9: Model Notice of Detention and Hearing

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Name, President
Company Name
Company Address

Re: NOTICE OF DETENTION AND HEARING
Entry Number (Assigned by Customs) (Product Name)

Dear (President's Name):

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, or the Act), as amended, 7 U.S.C. 136 et al., the United States Environmental Protection Agency has examined samples or other evidence concerning the shipment described below, and has determined that said shipment is in violation of the Act. You should continue to hold the merchandise pending a final decision as to whether it shall be admitted or refused admission.

Pursuant to Section 17(c) of the Act, the Agency hereby affords you an opportunity to offer such explanation as you wish for the Agency's consideration. You should file your answer, signed by you or your attorney, with this office within twenty (20) calendar days after your receipt of this Notice. Should you desire to present your views verbally, in addition to filing a written reply, you should advise us in your answer in order that we may set a date for such presentation, which should be held in this office or via teleconference.

Sample Number (if an inspection has been conducted):

Product Name:

Shipper/Manufacturer: Consignee:

Entry Number: Date of Importation: Port of Entry:

Upon examination, it appears the product(s) failed to comply with the provisions of the Act in that (describe violation). I am enclosing a copy of EPA's FIFRA Enforcement Response Policy, dated July 2, 1990.

Sincerely,
/s/
(Name and Title)

Enclosure

Exhibit 14-10

United States Customs Service, Treasury

§12.1

MERCHANDISE SUBJECT TO ECONOMIC
SANCTIONS

12.150 Merchandise prohibited by economic sanctions; detention; seizure or other disposition; blocked property.

AUTHORITY: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States (HTSUS)), 1624; Section 12.1 also issued under 21 U.S.C.371(b);

Section 12.3 also issued under 7 U.S.C. 135h, 21 U.S.C. 381(b);

Section 12.4 also issued under 21 U.S.C. 381(b);

Section 12.6 also issued under 7 U.S.C. 1854, 19 U.S.C. 1303;

Section 12.10 also issued under 7 U.S.C. 151– 162;

Section 12.15 also issued under 19 U.S.C. 1558;

Section 12.16 also issued under 7 U.S.C. 1592(b);

Sections 12.21 through 12.23 also issued under 42 U.S.C. 262;

Section 12.26 also issued under 18 U.S.C. 42; Section 12.28 also issued under 18 U.S.C. 42, 19 U.S.C. 1527;

Section 12.34 also issued under 19 U.S.C. 1202 (additional U.S. Note to Chapter 36, HTSUS);

Section 12.37 also issued under 27 U.S.C. 203;

Section 12.39 also issued under 19 U.S.C. 1337, 1623;

Sections 12.40 and 12.41 also issued under 19 U.S.C. 1305;

Sections 12.42 through 12.44 also issued under 19 U.S.C. 1307 and Pub. L. 105–61 (111 Stat. 1272);

Sections 12.73 and 12.74 also issued under 19 U.S.C. 1484, 42 U.S.C. 7522, 7601;

Section 12.85 also issued under 19 U.S.C. 1623, 46 U.S.C. 4302, 4306, 4310;

Sections 12.95 through 12.103 also issued under 15 U.S.C. 1241–1245;

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612.

Sections 12.105 through 12.109 also issued under 19 U.S.C. 2094;

Sections 12.110 through 12.117 also issued under 7 U.S.C. 136 *et seq.*;

Sections 12.118 through 12.127 also issued under 15 U.S.C. 2601 *et seq.*;

Sections 12.130 and 12.131 also issued under 7 U.S.C. 1854;

Section 12.140 also issued under 19 U.S.C. 1484, 2416(a), 2171;

Section 12.150 also issued under 19 U.S.C. 1595a and 1618; 22 U.S.C. 401.

EFFECTIVE DATE NOTE: By T.D. 01–26, 66 FR 16853, Mar. 28, 2001, in part 12, the specific authority citation for § 12.3 was revised, effective Apr. 27, 2001.

For the convenience of the user, the revised text is set forth as follows: Section 12.3 also issued under 7 U.S.C. 135h, 21 U.S.C. 381;

SOURCE: 28 FR 14710, Dec. 31, 1963, unless otherwise noted.

FOOD, DRUGS, AND COSMETICS, ECONOMIC
POISONS, HAZARDOUS SUBSTANCES, AND
DANGEROUS CAUSTIC OR CORROSIVE
SUBSTANCES**§12.1 Cooperation with certain agencies; joint regulations.**

(a) *Federal Food, Drug, and Cosmetic Act.* The importation into the United States of food, drugs, devices, and cosmetics as defined in section 201 (f), (g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (f), (g), (h), (i)) is governed by section 801 of the Act, as amended (21 U.S.C. 381) and regulations issued under authority of section 701(b) of the Act (21 U.S.C. 371(b)) by the Secretary of Health and Human Services and the Secretary of the Treasury (21 CFR 1.83 through 1.99).

(b) *Federal Insecticide, Fungicide, and Rodenticide Act.* The importation of pesticides and devices is governed by section 17(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136o(c)), and regulations issued under the authority of section 17(e) of that Act (7 U.S.C. 1360(e)) by the Secretary of the Treasury, in consultation with the Administrator of the Environmental Protection Agency, as set forth below (§ 12.110 *et seq.*).

(c) *Federal Hazardous Substances Act.* The importation of hazardous substances, misbranded hazardous substances, or banned hazardous substances as defined in section 2 of the Federal Hazardous Substances Act, as amended (15 U.S.C. 1261), is governed by regulations issued under the authority of sections 10(b) and 14 of the Act, as amended (15 U.S.C. 1269, 1273), by the Consumer Product Safety Commission (16 CFR 1500.265 through 1500.272).

[T.D. 68–191, 33 FR 11019, Aug. 2, 1968, as amended by T.D. 75–194, 40 FR 32321, Aug. 1, 1975; T.D. 82–145, 47 FR 35475, Aug. 16, 1982]

Exhibit 14-11

United States Customs Service, Treasury

§113.62**Subpart G—Customs Bond
Conditions****§ 113.61 General.**

Each section in this subpart identifies specific coverage for a particular Customs activity. When an individual or organization files a bond with Customs the activity in which they plan on engaging will be identified on the bond. The bond conditions listed in this subpart which correspond to that activity will be incorporated by reference into the bond.

§113.62 Basic importation and entry bond conditions.

A bond for basic importation and entry shall contain the conditions listed in this section and may be either a single entry or a continuous bond.

**BASIC IMPORTATION AND ENTRY BOND
CONDITIONS**

(a) *Agreement to Pay Duties, Taxes, and Charges.* (1) If merchandise is imported and released from Customs custody or withdrawn from a Customs bonded warehouse into the commerce of, or for consumption in, the United States, or under § 181.53 of this chapter is withdrawn from a duty-deferral program for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico, the obligors (principal and surety, jointly and severally) agree to:

(i) Deposit, within the time prescribed by law or regulation, any duties, taxes, and charges imposed, or estimated to be due, at the time of release or withdrawal; and

(ii) Pay, as demanded by Customs, all additional duties, taxes, and charges subsequently found due, legally fixed, and imposed on any entry secured by this bond.

(2) If the principal enters any merchandise into a Customs bonded warehouse, the obligors agree;

(i) To pay any duties, taxes, and charges found to be due on any of that merchandise which remains in the warehouse at the expiration of the warehousing time limit set by law; and

(ii) That the obligation to pay duties, taxes, and charges on the merchandise applies whether it is properly withdrawn by the principal, or by the principal's transferee, or is unlawfully removed by the principal or any other person, without regard to whether the merchandise is manipulated,

unless payment was made or secured to be made by some other person

regard to whether the merchandise is manipulated, unless payment was made or secured to be made by some other person.

(3) Under this agreement, the obligation to pay any and all duties, taxes, and charges due on any entry ceases on the date the principal timely files with the port director a bond of the owner in which the owner agrees to pay all duties, taxes, and charges found due on that entry; provided a declaration of the owner has also been properly filed.

(b) *Agreement to Make or Complete Entry.* If all or part of imported merchandise is released before entry under the provisions of the special delivery permit procedures under 19 U.S.C. 1448(b), released before completion of the entry under 19 U.S.C. 1484(a), or withdrawn from warehouse under 19 U.S.C. 1557(a) (see § 10.62b of this chapter), the principal agrees to file within the time and in the manner prescribed by law and regulation, documentation to enable Customs to:

(1) Determine whether the merchandise may be released from Customs custody;

(2) Properly assess duties on the merchandise;

(3) Collect accurate statistics with respect to the merchandise; and

(4) Determine whether applicable requirements of law and regulation are met.

(c) *Agreement to Produce Documents and Evidence.* If merchandise is released conditionally to the principal before all required documents or other evidence is produced, the principal agrees to furnish Customs with any document or evidence as required by law or regulation, and within the time specified by law or regulations.

(d) *Agreement to Redeliver Merchandise.* If merchandise is released conditionally from Customs custody to the principal before all required evidence is produced, before its quantity and value are determined, or before its right of admission into the United States is determined, the principal agrees to redeliver timely, on demand by Customs, the merchandise released if it:

(1) Fails to comply with the laws or regulations governing admission into the United States;

(2) Must be examined, inspected, or appraised as required by 19 U.S.C. 1499; or

(3) Must be marked with the country of origin

§113.62

as required by law or regulation. It is understood that any demand for redelivery will be made no later than 30 days after the date that the merchandise was released or 30 days after the end of the conditional release period (whichever is later).

(e) *Agreement to Rectify Any Non-Compliance with Provisions of Admission.* If merchandise is released conditionally to the principal before its right of admission into the United States is determined, the principal, after notification, agrees to mark, clean, fumigate, destroy, export or do any other thing to the merchandise in order to comply with the law and regulations governing its admission into the United States within the time period set in the notification.

(f) *Agreement for Examination of Merchandise.* If the principal obtains permission to have any merchandise examined elsewhere than at a wharf or other place in charge of a Customs officer, the principal agrees to:

(1) Hold the merchandise at the place of examination until the merchandise is properly released;

(2) Transfer the merchandise to another place on receipt of instructions from Customs made before release; and

(3) Keep any Customs seal or cording on the merchandise intact until the merchandise is examined by Customs.

(g) *Reimbursement and Exoneration of the United States.* The obligors agree to:

(1) Pay the compensation and expenses of any Customs officer, as required by law or regulation; and

(2) Exonerate the United States and its officers from any risk, loss, or expense arising out of principal's importation, entry, or withdrawal of merchandise.

(h) *Agreement on Duty-Free Entries or Withdrawals.* If the principal enters or withdraws any merchandise, without payment of duty and tax, or at a reduced rate of duty and tax, as permitted under the law, the principal agrees:

(1) To use and handle the merchandise in the manner and for the purpose entitling it to duty-free treatment;

(2) If a fishing vessel, to present the original approved application to Customs within 24 hours on each arrival of the vessel in the Customs territory of the United States from a fishing voyage;

(3) To furnish timely proof to Customs that any merchandise entered or withdrawn under any law

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permitting duty-free treatment was used in accordance with that law; and (4) To keep safely all withdrawn beverages remaining on board while the vessel is in port, as may be required by Customs.

(i) *Agreement to comply with Customs Regulations applicable to Customs security areas at airports.* If access to the Customs security areas at airports is desired, the principal (including its employees, agents, and contractors) agrees to comply with the Customs Regulations in this chapter applicable to Customs security areas at airports. If the principal defaults, the obligors (principal and surety, joint and severally) agree to pay liquidated damages of \$1000 for each default or such other amount as may be authorized by law or regulation.

(j) *Agreement to comply with electronic entry filing requirements.* If the principal is qualified to utilize electronic entry filing as provided for in part 143, subpart D, of this chapter, the principal agrees to comply with all conditions set forth in that subpart and to send and accept electronic transmissions without the necessity of paper copies.

(k) *Agreement to ensure and establish issuance of softwood lumber export permit and collection of export fees.* In the case of a softwood lumber product imported from Canada that is subject to the requirement that the Government of Canada issue an export permit pursuant to the Softwood Lumber Agreement, the principal agrees, as set forth in § 12.140(a) of this chapter, to assume the obligation to ensure within 20 working days of release of the merchandise, and establish to the satisfaction of Customs, that the applicable export permit has been issued by the Government of Canada.

(1) *Consequence of default.* (1) If the principal defaults on agreements in this condition other than conditions (a), (g), or (i) the obligors agree to pay liquidated damages equal to the value of the merchandise involved in the default, or three times the value of the merchandise involved in the default if the merchandise is restricted merchandise or alcoholic beverages, or such other amount as may be authorized by law or regulation.

(2) It is understood and agreed that whether the default involves merchandise is determined by Customs and that the amount to be collected under these conditions shall be based upon the quantity and value of the merchandise as determined by Customs. Value as used in these

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provisions means value as determined under 19 U.S.C. 1401a.

words ``or prohibited`` after the word ``restricted``, effective Apr. 27, 2001.

(3) If the principal defaults on agreements in this condition other than conditions (a) or (g) and the default does not involve merchandise, the obligors agree to pay liquidated damages of \$1,000 for each default or such other amount as may be authorized by law or regulation.

(4) If the principal defaults on agreements in the condition set forth in paragraph (a)(1)(i) of this section only, the obligors (principal and surety, jointly and severally) agree to pay liquidated damages equal to two times the unpaid duties, taxes and charges estimated to be due or \$1,000, whichever is greater. A default on the condition set forth in paragraph (a)(1)(i) of this section shall be presumed if any monetary instrument authorized for the payment of estimated duties, taxes and charges by § 24.1(a) of this chapter is returned unpaid by a financial institution, or if a payment authorized under Automated Clearinghouse (see § 24.25 of this chapter) is not transmitted electronically to Customs in a timely manner. If the principal defaults on agreements in both of the conditions as set forth in paragraphs (a)(1)(i) and (b) of this section, the measure of liquidated damages assessed shall be as provided in paragraph (l)(1) of this section for a default of the agreements in the condition set forth in paragraph (b) of this section. For purposes of this paragraph, the phrase ``unpaid duties, taxes and charges`` shall include any appropriate ad valorem fees described in § 24.23 of this chapter, fees relating to dutiable mail described in § 24.22(f) of this chapter, and harbor maintenance fees described in § 24.24(e)(3) (i) and (ii) of this chapter.

(5) If the principal defaults on agreements in the condition set forth in paragraph (k) of this section only, the obligors agree to pay liquidated damages equal to \$100 per thousand board feet of the imported lumber.

[T.D. 84-213, 49 FR 41171, Oct. 19, 1984, as amended by T.D. 88-46, 53 FR 29230, Aug. 3, 1988; T.D. 88-72, 53 FR 45902, Nov. 15, 1988; T.D. 90-92, 55 FR 49884, Dec. 3, 1990; T.D. 93-37, 58 FR 30984, May 28, 1993; T.D. 96-14, 61 FR 2911, Jan. 30, 1996;

T.D. 96-18, 61 FR 6780, Feb. 22, 1996; T.D. 97-9, 62 FR 8623, Feb. 26, 1997; T.D. 98-56, 63 FR 32945, June 16, 1998; T.D. 00-87, 65 FR 77815, Dec. 13, 2000]

EFFECTIVE DATE NOTE: By T.D. 01-26, 66 FR 16854, Mar. 28, 2001, in § 113.62, paragraph (l)(1) is amended by removing the words ``conditions (a), (g), or (i)`` and adding, in their place, the words

``conditions in paragraphs (a), (g), (i), or (k) of this section`` and by adding the

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Subpart C—Special Permit for Immediate Delivery

§ 142.21 Merchandise eligible for special permit for immediate delivery.

Merchandise may be released under a special permit for immediate delivery, in accordance with section 448(b), Tariff Act of 1930, as amended (19 U.S.C. 1448(b)), in the following circumstances:

(a) *Contiguous countries.* At the discretion of the port director, merchandise arriving by land from Canada or Mexico may be released under a special permit for immediate delivery provided the importer has on file a bond on Customs Form 301, containing the bond conditions set forth in § 113.62 of this chapter. An entry summary shall be filed in accordance with § 142.22(b)(1), and estimated duties, if any, shall be deposited, within the time period specified in § 142.23 for all merchandise from contiguous countries released under a special permit except for fresh fruits and vegetables for human consumption released under the provisions of paragraph (b) of this section.

(b) *Fresh fruits and vegetables.* (1) An application for a special permit for immediate delivery may be made for the transportation of fresh fruits and vegetables for human consumption arriving from Canada or Mexico to the importer's premises within the port of importation, but removed from the area immediately contiguous to the border.

(2) The application shall be accompanied by a continuous bond on Customs Form 301, containing the bond conditions set forth in § 113.62 of this chapter.

(3) The fresh fruits and vegetables shall be transported to the importer's premises in the vehicles in which they crossed the border or, if transshipment is necessary in vehicles provided by the importer. The fresh fruits and vegetables may be examined at the importer's premises. Those portions without commercial value may be disposed of in accordance

with the provisions of § 158.11(b) of this chapter, and the balance shall be entered for consumption or transported in bond under an entry for immediate transportation without appraisement or under an entry for transportation and exportation.

(c) *Agency of U.S. Government.* Merchandise may be released under the immediate delivery procedure if the shipment is consigned to or for the account of any agency or office of the United States Government, or to an officer or official of any such agency in his official capacity, as provided in § 10.101 of this chapter.

(d) *Articles of a trade fair.* Articles for a trade fair may be released under the immediate delivery procedure, as provided in § 147.13 of this chapter.

(e) *Quota-class merchandise—(1) Tariff rate.* At the discretion of the port director, merchandise subject to a tariff rate quota may be released under a special permit for immediate delivery provided the importer has on file a bond on Customs Form 301, containing the bond conditions set forth in § 113.62 of this chapter. An entry summary shall be properly presented pursuant to § 132.1 of this chapter within the time specified in § 142.23, or within the quota period, whichever expires first. If proper presentation is not made until after the tariff-rate quota is filled, the merchandise shall not be entitled to the quota rate of duty, and the importer shall pay duties at the over-quota rate.

(2) *Absolute.* At the discretion of the port director, perishable merchandise of a class approved by Customs Headquarters which is subject to an absolute quota may be released under a special permit for immediate delivery for removal to the importer's premises, or to any other location approved by the port director, until an entry summary is properly presented pursuant to § 132.1 of this chapter. A proper entry summary must be presented for merchandise so released within the time specified

in § 142.23, or within the quota period, whichever expires first. If the absolute quota is filled before the importer has properly presented an entry summary, he may either present an entry summary for warehouse or, under Customs supervision, export or destroy the merchandise.

(f) *Release from warehouse followed by warehouse withdrawal for consumption.*

Merchandise may be released from warehouse under a special permit:

(1) At the discretion of the port director when:

(i) The warehouse is located a considerable distance from the customhouse and actual release of the merchandise from the warehouse may not be effected within the next full business day after the day of the payment of duty, and

(ii) The port has sufficient manpower to permit such practice;

(2) The importer shall have on file a bond on Customs Form 301, containing the bond conditions set forth in § 113.62 of this chapter; and

(3) The immediate delivery permit shall be annotated to state that a warehouse withdrawal for consumption will be filed for this merchandise.

(g) *When authorized by Headquarters.* Headquarters may authorize the release of merchandise under the immediate delivery procedure in circumstances other than those described in paragraphs (a), (b), (c), (d), (e), and (f) of this section provided a bond on Customs Form 301, containing the bond conditions set forth in § 113.62 of this chapter is on file.

(R.S. 251, as amended, secs. 623, as amended, 624, 46 Stat. 759, as amended (19 U.S.C. 66, 1623, 1624)) [T.D. 79-221, 44 FR 46821, Aug. 9, 1979, as amended by T.D. 81-260, 46 FR 49842, Oct. 8, 1981; T.D. 84-213, 49 FR 41185, Oct. 19, 1984; T.D. 89-104, 54 FR 50499, Dec. 7, 1989]

§ 142.22 Application for special permit for immediate delivery.

(a) *Form.* An application for a special permit for immediate delivery shall be made on Customs Form 3461 supported

by the documentation provided for in § 142.3, except that a commercial invoice shall not be required. Instead of a commercial invoice, the importer may deliver to Customs a pro forma invoice, waybill, or other document setting forth an adequate description of the merchandise and the quantities, together with the values or approximate values when values are needed for the purpose of examination. If the merchandise is to be released under a term special permit, the documentation also shall show the term special permit number, as provided for in § 142.24.

(b) *Customs custody.* Merchandise for which a special permit for immediate delivery has been issued under § 142.21 of this part shall be considered to remain in Customs custody until the filing of one of the following:

(1) An entry summary for consumption, with estimated duties attached; an entry summary for consumption without estimated duties attached, if entry/entry summary information and a valid scheduled statement date (pursuant to § 24.25 of this chapter) have successfully been received by Customs via the Automated Broker Interface; an entry summary for warehouse; or an entry summary for entry temporarily under bond, which may be filed in any of the circumstances under § 142.21 of this part except for merchandise released from warehouse under § 142.21(f) of this part;

(2) A withdrawal for consumption, with estimated duties attached, which shall be filed only for merchandise released from warehouse under § 142.21(f) of this part;

(3) An entry for transportation and exportation, immediate transportation without appraisement, or direct exportation, which shall be filed in those circumstances under § 142.21(b) and (e)(2) of this part; or entry for transportation and exportation, or direct exportation, which shall be filed in the circumstances under § 142.28 of this part or

(4) An application to destroy, which shall be filed in those circumstances under §§ 142.21(b) and (e)(2), and § 142.28 of this part.

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(R.S. 251, as amended, secs. 623, as amended, 624, 46 Stat. 759, as amended (19 U.S.C. 66, 1623, 1624))

[T.D. 79-221, 44 FR 46821, Aug. 9, 1979, as amended by T.D. 81-260, 46 FR 49842, Oct. 8, 1981; T.D. 89-104, 54 FR 50499, Dec. 7, 1989]